Text input form

Please fill the white boxes with the information that should be written in the report. If you think you do not need to give an information, you can simply let the box empty.

# General information about the study

|  |  |
| --- | --- |
| **Type of study** |  |
| **Study number** |  |
| **Identification number** |  |
| **Number of participants** |  |
| **Number of critical tasks** |  |

# Cover page

## Title and subtitle

|  |  |
| --- | --- |
| **Title** |  |
| **Subtitle** |  |

## Information about document approval

|  |  |
| --- | --- |
| **Author’s name** |  |
| **Author’s function** |  |
| **Reviewer’s name** |  |
| **Reviewer’s function** |  |
| **Approver’s name** |  |
| **Approver’s function** |  |

## Picture

|  |  |
| --- | --- |
| **Picture name** | **Caption** |
| Cover\_page |  |

# Header

|  |  |
| --- | --- |
| **Firm name** |  |
| **Header title** |  |
| **Version / ID** |  |

# Purpose

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
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| Parameter 2 | {2} | - |

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| **Picture name** | **Caption** |
| Purpose1 |  |
| Purpose2 |  |
| Purpose3 |  |

# Background

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
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| Parameter 2 | {2} | - |

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| **Picture name** | **Caption** |
| Background1 |  |
| Background2 |  |
| Background3 |  |

# Scope

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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
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| Parameter 2 | {2} | - |

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| **Picture name** | **Caption** |
| Scope1 |  |
| Scope2 |  |
| Scope3 |  |

# Terms definitions

## EU Regulation 2017/745

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Medical device** | Yes |  | **Investigational device** | No |
| **Accessory for a medical device** | No |  | **Clinical investigation plan** | No |
| **Custom-made device** | No |  | **Clinical data** | No |
| **Active device** | No |  | **Subject** | No |
| **Implantable device** | No |  | **Clinical evidence** | No |
| **Invasive device** | No |  | **Clinical performance** | No |
| **Single-use device** | No |  | **Clinical benefit** | No |
| **Intended purpose** | No |  | **Investigator** | No |
| **Label** | No |  | **Informed consent** | No |
| **Instructions for use** | No |  | **Adverse event** | No |
| **Performance** | No |  | **Serious adverse event** | No |
| **Risk** | No |  | **Device deficiency** | No |
| **User** | No |  | **Withdrawal** | No |
| **Lay person** | No |  | **Incident** | No |
| **Clinical evaluation** | No |  | **Serious incident** | No |
| **Clinical investigation** | No |  |  |  |

## IEC 62366-1

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Abnormal use** | No |  | **Usability** | No |
| **Accompanying documentation** | No |  | **Usability engineering** | No |
| **Correct use** | No |  | **Use environment** | No |
| **Formative evaluation** | No |  | **Use error** | No |
| **Hazard-related use scenario** | No |  | **Use scenario** | No |
| **Normal use** | No |  | **Use specification** | No |
| **Patient** | No |  | **User** | No |
| **Primary operating function** | No |  | **User group** | No |
| **Summative evaluation** | No |  | **User interface** | No |
| **Task** | No |  | **User interface specification** | No |

## FDA Guidance

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Abnormal use** | No |  | **Human factors validation testing** | No |
| **Critical task** | No |  | **Task** | No |
| **Formative evaluation** | No |  | **Use error** | No |
| **Hazard** | No |  | **User** | No |
| **Hazardous situation** | No |  | **User interface** | No |
| **Human factors engineering** | No |  |  |  |

# Ethics statement

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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
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| **Picture name** | **Caption** |
| Ethics\_statement1 |  |
| Ethics\_statement2 |  |
| Ethics\_statement3 |  |

# Device specifications

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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| **Picture name** | **Caption** |
| Device\_specifications1 |  |
| Device\_specifications2 |  |
| Device\_specifications3 |  |

# Test procedure

## Goal

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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
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| Parameter 2 | {2} | - |

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| **Picture name** | **Caption** |
| Goal1 |  |
| Goal2 |  |
| Goal3 |  |

## Participants

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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Participants1 |  |
| Participants2 |  |
| Participants3 |  |

## Use environment

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Use\_environment1 |  |
| Use\_environment2 |  |
| Use\_environment3 |  |

## Use scenarios

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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Use\_scenarios1 |  |
| Use\_scenarios2 |  |
| Use\_scenarios3 |  |

## Setup

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Setup1 |  |
| Setup2 |  |
| Setup3 |  |

# Results

## Information about critical tasks

|  |  |  |
| --- | --- | --- |
| **Critical task** | **Name** | **Description** |
| Critical task 1 |  |  |
| Critical task 2 |  |  |
| Critical task 3 |  |  |
| Critical task 4 |  |  |
| Critical task 5 |  |  |
| Critical task 6 |  |  |
| Critical task 7 |  |  |
| Critical task 8 |  |  |
| Critical task 9 |  |  |
| Critical task 10 |  |  |
| Critical task 11 |  |  |
| Critical task 12 |  |  |
| Critical task 13 |  |  |
| Critical task 14 |  |  |
| Critical task 15 |  |  |

## Effectiveness analysis

|  |  |
| --- | --- |
| **Do you want to perform this analysis?** | Yes |

### Information about effectiveness analysis

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Critical task** | **P1** | **P2** | **P3** | **P4** | **P5** | **P6** | **P7** | **P8** | **P9** | **P10** | **P11** | **P12** | **P13** | **P14** | **P15** |
| Critical task 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 10 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 11 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 12 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 13 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 14 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 15 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Problem** | **Problem type** | **Problem description** |
| Problem 1 | - |  |
| Problem 2 | - |  |
| Problem 3 | - |  |
| Problem 4 | - |  |
| Problem 5 | - |  |
| Problem 6 | - |  |
| Problem 7 | - |  |
| Problem 8 | - |  |
| Problem 9 | - |  |
| Problem 10 | - |  |
| Problem 11 | - |  |
| Problem 12 | - |  |
| Problem 13 | - |  |
| Problem 14 | - |  |
| Problem 15 | - |  |

### Discussion

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

|  |  |
| --- | --- |
| **Picture name** | **Caption** |
| Effectiveness\_analysis1 |  |
| Effectiveness\_analysis2 |  |
| Effectiveness\_analysis3 |  |

## Time on tasks

|  |  |
| --- | --- |
| **Do you want to perform this analysis?** | Yes |

### Information about time on tasks analysis

|  |  |
| --- | --- |
| **Plot type** | Box plot |

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Critical task** | **P1** | **P2** | **P3** | **P4** | **P5** | **P6** | **P7** | **P8** | **P9** | **P10** | **P11** | **P12** | **P13** | **P14** | **P15** |
| Critical task 1 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 2 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 3 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 4 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 5 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 6 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 7 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 8 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 9 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 10 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 11 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 12 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 13 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 14 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Critical task 15 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

### Discussion

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| Please write the chapter text below: |
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| --- | --- | --- |
| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Time\_on\_tasks1 |  |
| Time\_on\_tasks2 |  |
| Time\_on\_tasks3 |  |

## Dwell times and revisits

|  |  |
| --- | --- |
| **Do you want to perform this analysis?** | Yes |

### Discussion

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Dwell\_times\_and\_revisits1 |  |
| Dwell\_times\_and\_revisits2 |  |
| Dwell\_times\_and\_revisits3 |  |

## Average fixation

|  |  |
| --- | --- |
| **Do you want to perform this analysis?** | Yes |

### Information about average fixation analysis

|  |  |
| --- | --- |
| **Plot type** | Box plot |

### Discussion

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Average\_fixation1 |  |
| Average\_fixation2 |  |
| Average\_fixation3 |  |

## Transitions

|  |  |
| --- | --- |
| **Do you want to perform this analysis?** | Yes |

### Discussion

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| Please write the chapter text below: |
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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| **Picture name** | **Caption** |
| Transitions1 |  |
| Transitions2 |  |
| Transitions3 |  |

# Conclusion

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| **Parameter** | **Reference** | **Value** |
| Parameter 0 | {0} | - |
| Parameter 1 | {1} | - |
| Parameter 2 | {2} | - |

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| --- | --- |
| **Picture name** | **Caption** |
| Conclusion1 |  |
| Conclusion2 |  |
| Conclusion3 |  |

# Appendix

## Participants characteristics

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Participant** | **Gender** | **Age** | **Function** | **Disease / Handicap** | **Experience** | **Known similar devices** |
| Participant 1 |  |  |  |  |  |  |
| Participant 2 |  |  |  |  |  |  |
| Participant 3 |  |  |  |  |  |  |
| Participant 4 |  |  |  |  |  |  |
| Participant 5 |  |  |  |  |  |  |
| Participant 6 |  |  |  |  |  |  |
| Participant 7 |  |  |  |  |  |  |
| Participant 8 |  |  |  |  |  |  |
| Participant 9 |  |  |  |  |  |  |
| Participant 10 |  |  |  |  |  |  |
| Participant 11 |  |  |  |  |  |  |
| Participant 12 |  |  |  |  |  |  |
| Participant 13 |  |  |  |  |  |  |
| Participant 14 |  |  |  |  |  |  |
| Participant 15 |  |  |  |  |  |  |